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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,139	12/27/2001	James Kelly Fox	G&C 130.40-US-01	1622
22462	7590	02/08/2005		
GATES & COOPER LLP HOWARD HUGHES CENTER 6701 CENTER DRIVE WEST, SUITE 1050 LOS ANGELES, CA 90045			EXAMINER NATNITHADHA, NAVIN.	
			ART UNIT 3736	PAPER NUMBER

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/034,139	<b>Applicant(s)</b> FOX ET AL.	
	<b>Examiner</b> Navin Natnithithadha	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) 57-110 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>09082003</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of claims 1-56 in the reply filed on November 17, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 57-110 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 17, 2004.

### ***Claim Objections***

3. Claim 1 is objected to because of the following informalities:

In line 6, it is unclear which element "provides an observable indicator..." It appears that the "processor" performs the above function. Therefore, the claim should be amended to - - wherein the processor provides an observable indicator... - -.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 3736

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3, 5-9, 11, 13-15, 23, 25, 27, 28-31, 33-37, 39, 41-43, 51-53, 55, and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Say et al, US 6,175,752

B1.

In regards to claims 1-3, 8, 29-31, and 36, Say teaches an analyte (physiological characteristic) monitor (see abstract) and method of monitoring analyte, specifically measuring the concentration of blood glucose. The analyte monitor comprising:

a receiver (input device) 150 receiving a signal from a sensor 42;

a processing circuit (processor) 109 analyzing the received signal;

wherein the processing circuit 109 repeatedly determining rate of change of analyte based on a series of sensor signals; and

wherein the processing circuit 109 provides an observable indicator 168 of certain conditions based on the level of analyte (see col. 50 line 11-31 and 52-65).

As to claims 5, 6, 14, 15, 23, 28, 33, 34, 42, 43, 51, 52, and 56, Say teaches determining an acceleration (slope) of an increase or decrease (increase or decrease slope) in the level of analyte reaches or exceeds a predetermined threshold value for hypoglycemic or hyperglycemic conditions (see col. 51, lines 29-36).

As to claims 7, 9, 25, 27, 35, 37, 53, and 55, Say teaches an indicator 168 and alarm system 156 in response to anticipated hypoglycemia (glucose crash or low glucose levels) 170 or anticipated hyperglycemia (high glucose levels) 172 (see col. 50, lines 59-65).

As to claims 11 and 39, Say teaches an indicator 168 and alarm system 156 in response to anticipated hypoglycemia (glucose crash or low glucose levels) 170 or anticipated hyperglycemia (high glucose levels) 172 (see col. 50, lines 59-65).

As to claims 13 and 41, Say teaches the alarm system 156 warns the patient of impending condition (hypoglycemia or hyperglycemia) when the rate or acceleration (slope) of an increase or decrease in analyte level reaches or exceeds a threshold value (see col. 51, lines 29-36).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 4, 16, 17, 19-22, 32, 44-46, and 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Say et al, US 6,175,752 B1, as applied to claims 3 and 31 above, and further in view of Mault et al, US 2003/0208113 A1.

As to claims 4, 16, 32, and 44, the claimed subject matter is a well-known function of fitting a curve to a series of values in a data stream. Mault teaches fitting a curve 342 to data by a computer, i.e. processing circuit, to a series of blood glucose measurements over a period of time (see fig. 12 and paragraph [0126]). It would have been obvious for one of ordinary skill in the art at the time the invention was made to

modify Say's processing circuit to include a "curve fitting" function in order to visually model the person's glycemic response.

As to claims 17 and 45, Say teaches the alarm system 156 warns the patient of impending hypoglycemia or impending hyperglycemia (see col. 51, lines 19-28). It is possible that these conditions may occur in the morning and, therefore, the alarm system 156 would warn the patient of impending morning hypoglycemia/hyperglycemia.

As to claims 19 and 46, Say teaches determining an acceleration (slope) of an increase or decrease (increase or decrease slope) in the level of analyte (see col. 51, lines 29-32) and averaging a series datapoints (see col. 51, lines 29-50). In addition, Mault teaches analyzing the curve for rise slope behavior and decay slope behavior in the data (see paragraph [0126]).

As to claims 20 and 48, Say teaches anticipating hypoglycemia or hyperglycemia in a period of time spanning a predetermined number of hours (see fig. 12). Any of these values on the curve in Figure 12 could be determined approximately three hours before an anticipated wakeup time.

As to claims 21, 22, 49, and 50, Say teaches exceeds predetermined threshold values for hypoglycemic or hyperglycemic conditions.

6. Claims 10, 12, 18, 26, 38, 40, 46, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Say et al, US 6,175,752 B1, as applied to claim 3, 5, 16, 23, 31, 33, 44, 51 above, and further in view of Houben et al, US 6,572,542 B1.

As to claims 10, 12, 18, 26, 38, 40, 46, and 54, Say does not specifically teach the series of data corresponding to the level of analyte, or glucose, spans a time period of approximately ten, thirty, or sixty minutes. However, Houben teaches monitoring glucose in a span a time, which covers the specified time period claimed (see fig. 12). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Say's processing circuit to monitor a series of data in order to provide accurate warning to a hypoglycemic or hyperglycemic event.

### ***Conclusion***

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Navin Natnithithadha whose telephone number is (571) 272-4732. The examiner can normally be reached on Monday-Friday, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3736

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Navin Natnithithadha  
Patent Examiner  
GAU 3736  
February 7, 2005



ROBERT S. MASSEY  
PATENT EXAMINER